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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,103

03/10/2006

Ian Wilson

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12/07/2009

GE HEALTHCARE, INC.

IP DEPARTMENT 101 CARNEGIE CENTER

PRINCETON, NJ 08540-6231

EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,103	<b>Applicant(s)</b> WILSON ET AL.	
	<b>Examiner</b> MELISSA PERREIRA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 9-16,31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,17-30,33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/1/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 1-34 are pending in the application.
2. Applicant's election without traverse of the species of "radioactive metal ion" in the reply filed on 10/7/09 is acknowledged.
3. Claims 9-16,31 and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/7/09.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 33 and 34 provides for the use of an imaging agent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 33 and 34 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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6. Claims 3 and 4 recites the limitation "imaging moiety" in regards to R<sup>1</sup> to R<sup>14</sup>.

There is insufficient antecedent basis for this limitation in the claim as claim 2 doesn't include an imaging moiety for R<sup>1</sup> to R<sup>14</sup> which are independently R.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

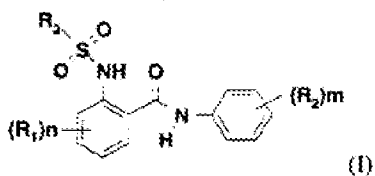
8. Claims 1-8 and 17-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (WO02/067761) in view of Weinstock et al. (WO00/78145A1)

9. Edwards et al. (WO02/067761) discloses detectably labeled macrophage scavenger receptor antagonist (MSRA) complexes for the diagnosis and monitoring of various cardiovascular diseases including but not limited to atherosclerosis, coronary artery disease, renal disease, thrombosis, transient ischemia, etc. (abstract; p37, lines 12-18). The complexes of the disclosure include M-C<sub>h</sub>-L<sub>n</sub>-(BM)<sub>n</sub> wherein M is a radionuclide (i.e. <sup>99m</sup>Tc, <sup>111</sup>In, <sup>113m</sup>In, etc.; C<sub>h</sub> is a metal chelator (i.e. a N<sub>4</sub> ligand, N<sub>2</sub>S<sub>2</sub> ligand); L<sub>n</sub> is a linking group; and BM is a MSRA antagonist (p18-23; p26, lines 19+; p50, lines 6+; see claims). Edwards et al. also teaches of kits comprising the MSRAs of the disclosure (claims 38+).

10. Edwards et al. does not disclose a sulphonamidobenzamide MSRA.

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11. Weinstock et al. (WO00/78145A1) discloses sulphonamidobenzamide macrophage scavenger receptor antagonists (MSRA) (below) for treating cardiovascular disease including but not limited to atherosclerosis, coronary artery disease, renal disease, thrombosis, transient ischemia, etc. (abstract; p2, lines 26+; p3, lines 8+).  $R_3$  may be  $R_1$ aryl, etc. The MSRAs may be formulated as pharmaceutical compositions and administered as tablets, liquid preparations, etc. (p11, lines 14+).



12.

13. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute one macrophage scavenger receptor antagonist (MSRA), such as that of Weinstock et al. for another analogous macrophage scavenger receptor antagonist (MSRA), such as that of Edwards et al. as both are used for treating cardiovascular diseases. Also, the simple substitution of one known, equivalent element for another yields predictable results, such as binding macrophage scavenger receptors.

14. Edwards et al. does not explicitly disclose the imaging agent precursor of Formula (IIIa), claim 20.

15. At the time of the invention it would have been obvious to one ordinarily skilled in the art that the  $M-C_h-L_n-(BM)_n$  of Edwards et al. comprises a  $C_h-L_n-(BM)_n$  (imaging agent precursor) prior to chelation of a radionuclide (i.e.  $^{99m}\text{Tc}$ ,  $^{111}\text{In}$ ,  $^{113m}\text{In}$ , etc.) as the  $^{99m}\text{Tc}$ -

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labeling of a (BFC) bifunctional chelator-derivatized SR-A receptor antagonist is accomplished by adding [ $^{99m}\text{Tc}$ ]pertechnetate to the kit comprising a BFC-derivatized SR-A receptor antagonist/ imaging agent precursor (Edwards et al. p51, lines 1-15). Thus, the precursors provide the advantage of providing a kit that may be radiolabeled at a later date, prior to use.

### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/  
Examiner, Art Unit 1618